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09/864,510	05/24/2001	Gregory Murphy	28122.89	2445

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EXAMINER	
LEWIS, RALPH A	

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/864,510	MURPHY ET AL
	Examiner	Art Unit
	Ralph A. Lewis	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 29-194* is/are pending in the application.

4a) Of the above claim(s) *13,14,71-73,96-98,141-145,154,155,168 and 169* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,29-70,74-95,99-140,146-154,157-165 and 168-194* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14,17,19,20*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Acknowledgement of Election

Applicant's election without traverse of the Invention Species I directed to a balloon shaper and method of use as depicted in Figures 2a-2f in paper number 18, received May 16, 2003 is acknowledged. Claims 13, 14, 71-73, 96-98, 141-145, 155, 156, 166 and 167 are withdrawn from further consideration as being directed to a nonelected invention.

Rejections based on Obvious-type double patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.d. 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 29-70, 74-95, 99-140, 146-154, 157-165 and 168-194 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent 6,681,773 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

ordinarily skilled artisan would have found it obvious to have claimed only a single element of the "kit" set forth in the allowed claims of 6,681,773 B2. The ordinarily skilled artisan would have also found it obvious to eliminate steps set forth in the allowed method claims 19-28 of application 6,681,773 B2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Rejections based on 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 29-35, 45-47, 49-70, 74-95, 99-140, 146-154 and 157-165 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response to the previous Office Action on the merits applicant amended the claims to emphasize that the required size and shape for the shaper is "similar to the size and shape of an appropriate left ventricle" which is "less than the size of the enlarge left ventricle" and argues that the size and shape limitation is critical in distinguishing the claimed device from that of the prior art. Applicant states that "Deslauriers does not appear to teach or suggest a shaper of substantially equal size and shape of an appropriate left ventricle" (response page 22).

Applicant's specification indicates that the "size and shape of an appropriate left ventricle" is determined by "a surgeon" (page 10, line 17) and that the length of the balloon shaping device "may vary with each patient and will typically be a function of the volume selected for the shaping device" (page 10, lines 14-16). The specification continues with a specific example, but then admonishes the reader that it "is not meant to limit the invention to the above ratios or shapes" (page 1, lines 13-15). Claims 32-35, indicate that the critical shape can actually be a variety of different shapes and the specification includes a specific example wherein the critically claimed "size or volume of this embodiment may be controlled by controlling the amount and pressure of fluid injected into the balloon" (page 13, lines 15 and 16).

It appears to this examiner that the claimed "size and shape of an appropriate left ventricle" limitation argued by applicant to be critical to patentability of the apparatus depends on not any specific parameters in the claims or specification, but rather on the size of some undefined patient[1], the size and shape a surgeon determines to be "appropriate" and/or even the amount of fluid that happens to be injected into a balloon shaper. The examiner cited Deslauriers et al (Figure 2) illustrating a balloon substantially sized and shaped such that it fits within and occupies a left ventricle, despite the Figure clearly showing the size and shape limitation applicant has chosen to argue that the Deslauriers et al balloon doesn't meet the "size and shape of an

[1] Note *Ex Parte Brumer*, 12 USPQ 2d 1654 (1989, Bd of Appeals) where the Board held an apparatus claim with size limitations directed to the size of a user indefinite under 35 U.S.C. 112, second paragraph.

appropriate left ventricle" limitation. With such a position taken by applicant, the examiner is at a loss as to how anyone could possibly determine with any degree of objectivity whether a given balloon device meets the "size and shape of an appropriate left ventricle" limitation. This critical limitation (as applicant is interpreting it) fails to reasonably inform the public of what apparatuses fall within the bounds of the claim and which apparatuses do not.

Additionally, in claim 48, line 3, "sharper"?

In claim 176, there is no antecedent basis for "the viable tissue." It appears that the claim should be dependent upon claim 170. It is also noted that claim 174 would also more logically follow from claim 170, rather than claim 168.

In claim 185, there is no antecedent basis for "the viable tissue." It appears that the claim should be dependent upon claim 179. It is also noted that claim 183 would more logically follow from claim 179, rather than claim 177.

In claim 194, there is no antecedent basis for "the viable tissue." It appears that the claim should be dependent upon claim 188. It is also noted that claim 192 would more logically follow from claim 188, rather than claim 186.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8-12, 29-35, 45-47, 49, 50, 53-70, 74, 75, 78-95, 104-116, 119-138, 146-154, 157-165, 168, 169, 186 and 187 are rejected under 35 U.S.C. 102(b) as being anticipated by Deslauriers et al (5,255,678).

Deslauriers et al disclose in Figure 2 a balloon device 20 that is shaped and sized to fit within and occupy a patient's left ventricle 40 when inflated. The device further includes a tube 23 in fluid communication with the balloon 20, a valve 24, pressure gauge (column 8, line 65) and syringe 26. The purpose for which applicant intends the balloon device to be used (i.e. a "shaper") fails to impose any objectively ascertainable structural distinctions from the device disclosed by Deslauriers et al. In regard to claim 3, note (column 18, lines 15-18). In regard to claims 29-35 note the different shapes in Figures 9 and 10. In regard to claim 31, the proportions of Figure 9 meet the "about" limitation. In regard to claims 53 and 78, wall thickness of a balloon member inherently varies as the balloon is expanded. In regard to claims 57, 58, 82, 83, 108, 109, 131, and 132, the Deslauriers et al balloon is capable of being inflated with different types of fluid[2]. In regard to claims 104-116, and 119-123 the knitting of

[2] In claims 5-7, applicant positively claims the fluid as part of the claimed balloon, whereas in claims 57, 58, 82, 83, 108, 109, 131, and 132 applicant only claims that the balloon is configured to contain particular types of fluid. Accordingly, claims 57, 58, 82, 83, 108, 109, 131, and 132 are interpreted as claiming only the balloon and not the combination of balloon and fluid.

Deslauriers et al meets the claimed shaper limitations and the elastic balloon portion meets the claimed expander limitations. Additionally, in regard to claim 114, Deslauriers et al discloses a fluid (column 12, line 9) capable of being positioned between the knitting and the elastic member. In regard to claims 124-137, the elastic member of Deslauriers et al meets the shaper limitations and the knitting/electrodes of Deslauriers et al meet the "spacer" limitations. In regard to claim 138, note the bumpy portions 12 on the Deslauriers et al expandable balloon that have a thickness greater than the surrounding portions of the balloon. In regard to claims 168 and 169, note column 13, lines 25-28, where the left ventricle is reshaped to conform to the shape of the balloon.

In response to the present rejection applicant refers to passages in Deslauriers et al that discuss a knitting which forms part of the balloon structure and that the construction is adaptable to any of the four heart chambers. In regard to the "knitting" structure disclosed by Deslauriers et al, the present claims all include the terminology "comprising" and "comprises" clearly indicating that the claim includes within its scope shapers having elements other than those specifically set forth in the claims. Moreover, it is noted that the knitting structure of the Deslauriers et al balloon helps the balloon to maintain its desired shape (column 16, line 68) and limits the inflation of the balloon to a predetermined volume (column 18, lines 15-18). In regard to the disclosure that the structure is adaptable to any of the four heart chambers, Deslauriers et al discloses specifically shaped balloons for the left ventricle (Figures 9 and 10), as well as, specifically shaped balloons for the other ventricles (Figures 8, 11, 12). More

particularly, for a left ventricle having a pathological condition the balloon is shaped to be en elongated ellipsoidal shape (Figure 9), whereas for a normal shaped left vertical it is more of a cone/drop/pear shape (Figure 10). The Figure 9 and 10 left ventricle balloon embodiments of Deslauriers et al meet the "appropriate size and shape" limitations of the present claims.

Claims 1, 2, 36, 43, 45, 46, 48-50, 53-58, 64, 65, 74, 75, 78-83, 86, 90, 146-149, 153, 157-160, 164, 168, 169, 186, and 187 are rejected under 35 U.S.C. 102(b) as being anticipated by V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52).

Note Figure 2 and the second column of page 48 which discloses the repair of a patient's heart wherein an appropriately shaped balloon is inserted into the patient's left ventricle and inflated to the appropriate size (volume) and then deflated and removed once the left ventricle has been appropriately shaped.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7, 57, 58, 82, 83, 99-103, 108, 109, 117, 118, 131, 132, 177 and 178 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deslauriers et al (US 5,255,678) in view of Hillegass et al (US 4,817,637), Kovacs (US 5,749,839) and Cook et al (US 5,964,806).

Deslauriers et al indicates that the balloon member is filled with a saline solution rather than the claimed silicone gel. The prior art, however, is replete with teachings that silicone gel may conventionally be used in place of saline for inflating medical balloon devices as is evidenced for example by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al (column 3, lines 49-53). To have selected silicone gel rather than saline for the balloon inflation fluid as is well known in the art would have been obvious to the ordinarily skilled artisan. In regard to claims 57, 58, 82, 83, 108, 109, 131, and 132, to the extent that one interprets the fluid to be positively claimed, the present rejection applies.

Claims 51, 52, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deslauriers et al (5,255,678).

One of ordinary skill in the art would have found the manufacture of the Deslauriers et al device with the particular thickness dimension claimed obvious as a matter of routine.

Claims 3-5, 47, 51, 52, 59, 60, 76, 77, 84, 85, 150, 151, 161 and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52).

V. Dor et al fail to disclose that the balloon once fully inflated that it cannot be substantially further expanded or that the balloon maintains its shape while being inflated, however, one of ordinary skill in the art would have found such limitations obvious in the design and construction of the disclosed balloon. The ordinarily skilled artisan would have been motivated to use a balloon that resisted further filling once full so as to not provide for too large of a size during the V. Dor et al procedure and certainly the ordinarily skilled artisan would desire a balloon that maintained it shape during this critical open heart surgery. In regard to claims 51, 52, 76 and 77, the claimed wall thickness for the balloon fall well within a range one of ordinary skill in the art would have found to have been obvious in constructing the V. Dor et al balloon.

Claims 6, 7, 57, 58, 82, 83, 99, 100, 177 and 178 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) in view of Hillegass et al (US 4,817,637), Kovacs (US 5,749,839) and Cook et al (US 5,964,806).

V. Dor et al fails to disclose what type of fluid is used to inflate the disclosed balloon. The prior art, however, is replete with teachings that silicone gel may conventionally be used for inflating medical balloon devices as is evidenced for example

by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al (column 3, lines 49-53). To have selected silicone gel for the balloon inflation fluid as is well known in the art would have been obvious to the ordinarily skilled artisan. In regard to claims 57, 58, 82, and 83, to the extent that one interprets the fluid to be positively claimed, the present rejection applies.

Claims 8-12, 32-35, 61-70, 87-89, 91-95 152, 154, 163 and 165 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) in view of Deslauriers et al (5,255,678).

In regard to claims 8-12, 61-63, 87-89, 152 and 163, V. Dor et al fail to disclose the specifically claimed structures in regard to the disclosed balloon. Deslauriers et al, however, for a similar balloon used in the left ventricle teaches that a tube for conveying the inflation fluid, the use of a valve, pressure gauge and syringe are all desirable for controlling the inflation of a left ventricle balloon. To have merely used such common prior art features for controlling the inflation of the V.Dor et al balloon would have been obvious to one of ordinary skill in the art. In regard to claims 32-35, 64, 66-70, 91-95, 154 and 165, V.Dor et al fail to disclose the actual shape of the disclosed balloon. Deslauriers et al, however, teaches that it is desirable to form left ventricle balloons in the shape of a left ventricle which may be either ellipsoidal shape as in Figure 9 or drop/pear/cone shaped as in Figure 10. To have shaped the V.Dor et al balloon so that

it was the shape of the left ventricle as taught by Deslauriers et al would have been obvious to one of ordinary skill in the art.

Claims 101-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) in view of Hillegass et al (US 4,817,637), Kovacs (US 5,749,839) and Cook et al (US 5,964,806) as applied above and in further view of Deslauriers et al (US 5,255,678).

V. Dor et al fail to disclose the specifically claimed structures in regard to the disclosed balloon. Deslauriers et al, however, for a similar balloon used in the left ventricle teaches that a tube for conveying the inflation fluid, the use of a valve, pressure gauge and syringe are all desirable for controlling the inflation of a left ventricle balloon. To have merely used such common prior art features for controlling the inflation of the V.Dor et al balloon would have been obvious to one of ordinary skill in the art.

Allowable Subject Matter

The indicated allowability over the prior art of claims 36, 43 and 48 is withdrawn in light of the rejection above based on Prior Art filed by applicant after the first Office Action.

Claims 37-42, 44, 139, 140, 170-176, 179-185, and 188-194 would be allowable if a terminal disclaimer were filed to overcome the obvious-type double patenting

rejection and the claims written in independent form to include all of the limitations of the claims from which they depend and to overcome the rejections based on 35 U.S.C. 112, second paragraph above.

Prior Art

Applicant's information disclosure statements of May 15, 2003, May 19, 2003, January 27, 2003, and July 30, 2003 have been considered and an initialed copy enclosed herewith.

Action Made Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Ralph Lewis at telephone number (703) 308-0770. Fax (703) 872-9306. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (703) 308-2582.

R.Lewis
February 13, 2004

Ralph A. Lewis
Primary Examiner
Au3732